REMARKS

By way of summary, Claims 1, 2, 9, 10, 16, 17, 25 - 27 were pending in this application. This Final Office Action newly rejects Claims 1, 2, 9 and 16 under 35 U.S.C. § 102(e) as being anticipated by Scholten et al., U.S. Patent No. 4,969,888. The Final Office Action rejects Claims 10 and 25-27 under 35 U.S.C. § 103(a) as being obvious over the Scholten patent alone, and rejects Claim 17 under 35 U.S.C. § 103(a) as being obvious over the Scholten patent in view of Beyar et al., U.S. Patent No. 6,127,597.

In this Amendment, Claims 1, 2, 9, 10, 16, 17 and 25 have been amended to more clearly define the structure of the subject matter for which protection is sought. The Applicant respectfully submits that each of these amendments is supported by the specification, drawings, or original claim limitations and does not add new matter. The Applicant respectfully submits that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. Accordingly, Applicant reserves the right to pursue the previously unamended claims or claims of broader scope at a later date. Thus, Claims 1, 2, 9, 10, 16, 17 and 25-27 are pending for consideration in light of the foregoing amendments and following remarks.

Power of Attorney and Correspondence Address

Applicant respectfully requests future electronic correspondence be sent to Customer Number 20,995 as requested in Change of Correspondence Address filed November 13, 2007 and no more paper correspondence be sent to previous counsel Mirick, O'Connell, Demallie & Lougee, LLP as listed on the outstanding Office Action. Further, per the Power of Attorney filed December 19, 2008, Applicant has given Knobbe, Martens, Olson & Bear, LLP under Customer Number 20,995. Please direct all correspondence in electronic format when available to Customer Number 20,995 under Attorney Reference NLIGN.001A.

The Scholten Reference

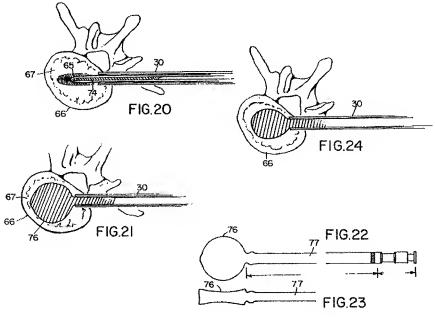
Scholten et al., U.S. Patent No. 4,969,888, discloses a balloon 76 permanently attached to a neck 77 that can be centered in bone after a separate, elliptical balloon 65 creates a cavity and is removed. Neither balloon 76 nor 65 is releasable from its neck, and both are inflated through

direct contact with bone (with no intermediary structures) to define a cavity in the bone. Scholten states:

> The next step to be performed in carrying out the method of the present invention is to withdraw the pointed guide pin 70 and replace it with a **deflated elliptical device or chambered bladder or balloon 65**. The elliptical balloon 65 is monitored fluoroscopically. This is achieved by inflating the elliptical balloon 65 to a pressure in the range of 50 to 300 psi with a radio-opaque contrast medium by an injector as shown in FIG. 24. The purpose of the elliptical balloon 65 is to center a second, checker-shaped inflatable device or balloon 76 (FIGS. 21-23) in the interior of vertebral body 66. **After the elliptical balloon is deflated and removed, checker-shaped or cylindrically shaped device of balloon 76 is inserted into the cannula and directed into the interior of vertebral body 66 as shown in FIG. 21**.
>
> The diameter of balloon 76 is determined by the pre-operative CAT-scan results. The diameter is in the range of 1.0 cm to 3.5 cm. The axial height of the balloon (FIG. 23) is determined by the intra-operative reduction height of the vertebral body fracture. The height is in the range of 0.5 cm to 4.0 cm. If the balloon placement is somewhat eccentric, a smaller balloon may be needed. **The balloon 76 has a neck 77, and the outer configuration of the balloon 76 is substantially the same as that of the inner surface of the cortical wall of the vertebral body 66.**
>
> The progress of balloon inflation is monitored fluoroscopically to ensure proper insertion of the balloon 76. The balloon is injected, gradually, with contrast as in the case of the elliptical balloon to a maximum height. This may require pressure as great as 300 psi to accomplish. The balloon's inflation should be monitored on the lateral fluoroscopic view of the spine. **Posterior displacement of the bone into the spinal canal or full expansion of balloon 76 signals the termination of the chamber preparation. Further expansion of the balloon at this point could result in spinal cord or root injury.**
>
> **As balloon 76 is inflated, it forces the osteoporotic bone marrow 67 laterally and outwardly of the wall of the vertebral body 66. This compacts the bone marrow and leaves a void in the interior of the vertebral body to be treated.** The compacted bone marrow forms a dam to block any fracture of the vertebral body. Thus, when liquid synthetic bone or methyl methacrylate cement is forced into the void, the compacted bone marrow will substantially prevent flow through the fracture.
>
> **After the balloon 76 has been deflated it is removed from the cannula 30. An irrigation nozzle (not shown) is then inserted into the vertebral body 66. Irrigation is performed with normal saline solution. Irrigation should be performed until the effluent is reasonably clear.**

After the vertebral body has been irrigated, the artificial bone substitute, which may include a synthetic bone or methyl methacrylate cement, is injected into the void left by the inflation of balloon 76. ...

Scholten at col. 6, line 47 – col. 7, line 27. Scholten Figures show:



The Office Action characterizes neck 77 as a "delivery catheter 77" at page 2. No balloon is "releasably carried by the delivery catheter" or detachable from its inflation neck 77 despite the characterization in the Office Action. Further, all expandable devices disclosed in Scholten are removed from the bone: "After the balloon 76 has been deflated it is removed from the cannula 30. An irrigation nozzle (not shown) is then inserted into the vertebral body 66 ..." then "After the vertebral body has been irrigated, the artificial bone substitute, which may include a synthetic bone or methyl methacrylate cement, is injected into the void left by the inflation of balloon 76. "

The Amended Claims are not anticipated nor rendered obvious by Scholten

Amended Claim 1 recites, in part, "an expandable implant for occupying space within bones, releasably carried by the delivery catheter; and an inflatable means of expanding the expandable implant, the inflatable means of expanding configured for removal from the bone upon expansion of the expandable implant; whereby the expandable implant mechanically is configured to fixate the fracture after the delivery catheter and the inflatable means of expanding the expandable implant are removed from the bone, leaving the expandable implant within the

bone." Scholten's implant is hardened synthetic bone or methyl methacrylate cement. Scholten's synthetic bone or methyl methacrylate cement is injected in to bone after removal of balloons. Scholten's balloons are not "inflatable means of expanding the expandable implant." Instead, Scholten's balloons create a cavity in bone and have nothing to do with expanding synthetic bone or methyl methacrylate cement.

Likewise, with respect to Amended Claim 2, Scholten's balloons have nothing to do with "expanding the expandable implant"—the balloons create cavities in bone, they are not "means of expanding the expandable implant" as claimed in independent Claim 1. Claim 9 depends from Claim 1 and is patentable for the reasons listed above, as well as for patentable reasons therein.

Amended Claim 16 recites, in part, "an expandable tubular implant, a delivery device comprising a balloon, the balloon having an exterior surface; said expandable tubular implant removably attached to the exterior surface of the balloon; whereby the balloon expands the tubular implant at the treatment site, whereby the balloon is configured to be removed after leaving the expanded tubular implant in place to span bone segments." Scholten's synthetic bone or methyl methacrylate cement is not "an expandable tubular implant." Scholten's synthetic bone or methyl methacrylate cement is not "removably attached to the exterior surface of the balloon." Scholten's balloon does not "expand[s] the tubular implant at the treatment site." Furthermore, Scholten's balloon are removed BEFORE any implant is inserted, thus Scholten does not have a "balloon [is] configured to be removed after leaving the expanded tubular implant in place to span bone segments."

Amended Claim 16 recites, in part, "disposing the expandable implant upon a delivery device, the delivery device comprising a balloon." Scholten's synthetic bone or methyl methacrylate cement "implants" are never place in contact with Scholten's balloons. Amended Claim 16 recites, in part, "inflating the balloon in order to cause expansion of the expandable implant." Again, Scholten's balloons are not inflated "in order to cause expansion of the expandable implant." Claims 25 and 26 depend from Claim 16 and are patentable for at least the reasons described with respect to independent Claim 16, as well as for patentable reasons in each of Claims 25 and 26.

Applicant respectfully request the withdrawal of all rejections based on Scholten for at least the reasons discussed above.

The Beyar Reference

Beyar et al., U.S. Patent No. 6,127,597, discloses a balloon fixture (also called an expandable intramedullary fixture) 80 comprising a balloon 82 and an inflation tube 88. Col. 26, line 64 – Col. 27, line 9. Figures from Beyar are provided below for the Examiner's convenience:

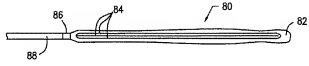


FIG. 6

Figs. 7A-7D show the use of balloon fixture 80 in fixating fractured bone 42 through a hole 45 at an end of the fractured bone 42.

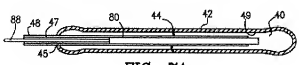


FIG. 7A

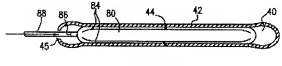


FIG. 7C

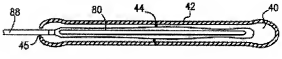


FIG. 7B

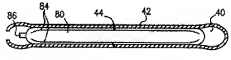


FIG. 7D

The Beyar device involves inserting the balloon 82, filling it with a solidifying fluid "to fixate the bone" and removing the inflation tube 88: "As shown in FIG. 7D, after balloon 82 has been filled and the fluid has at least partly solidified, inlet port 86 is sealed shut, and tube 88 is withdrawn. Within a short time, the solidified fluid fully hardens, anchoring fixture 80 in place and fixating bone 42." Col. 28, lines 1 – 5. The balloon 82 acts as an implant with a hardened medium contained inside of it, and is left in the bone 42. As discussed in the previous Response, during the Phone Interview of December 11, 2008, the Examiner noted that Beyer col. 28, line 16 as disclosing removal of the Beyar balloon fixture 80 after the bone has healed: "If desired, after bone 42 has healed, fixture 80 may be removed through hole 45 or via an osteotomy elsewhere in

bone 42. Preferably, at least a portion of the solidified fluid is drilled out or broken up, and the fixture is then collapsed and removed."

Claim 17 is not rendered obvious by Scholten in view of Beyar

Claim 17 depends from Independent Claim 16, and is patentable for the reasons described above with respect to Claim 16 as well as for patentable aspects of Claim 17. The Office Action characterizes Scholten as not disclosing "an expandable device that comprises a tubular mesh." Beyar does not cure the deficiencies of the Scholten reference, as discussed above with respect to at least Claim 16. Accordingly, at least Claim 17 is allowable over Scholten in view of Beyar. Applicant respectfully requests the withdrawal of the rejections based on Scholten in view of Beyar.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending application, which contains a known priority relationship to the present application.

Serial Number	Title	Filed
12/011,115	METHOD AND DEVICES FOR THE TREATMENT OF NASAL SINUS DISORDERS	01/23/2008
12/258,309	METHODS AND DEVICES FOR TREATMENT OF BONE FRACTURES	10/24/2008

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 6-18-09

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